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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,462	05/01/2001	Jehad Charo	1430-264	7394

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EXAMINER
QIAN, CELINE X

ART UNIT	PAPER NUMBER
1633	8

DATE MAILED: 01/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/763,462	CHARO ET AL.	
	Examiner	Art Unit	
	Celine Qian	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *14-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,7-13 and 24* is/are rejected.

7)☒ Claim(s) *2-4 and 6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☑ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-24 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group I and 4-(2-formyl-3-hydroxyphenoxymethyl) benzoic acid in Paper No. 7 is acknowledged. The traversal is on the ground(s) that claims of Group II are being linked to Group I and III as a product, a method of use and a method of manufacture. Applicants further argue that all the compounds recited in claim 1 are Schiff base forming compounds and therefore are not distinct inventions.

This is not found persuasive because there is no special technical feature between the groups. According to 37 C.F.R 1.475 (a) "Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." The vaccine composition comprising 4-(2-formyl-3-hydroxyphenoxymethyl) benzoic acid being used as an adjuvant does not define a contribution over the prior art because the disclosure of such use in US 5,508,310 (see column 9, 7th paragraph). Therefore, there is no special technical feature between inventions of Groups I-III.

The requirement is still deemed proper and is therefore made FINAL.

Regarding the Markush group in claim 1, applicant's argument that all the compounds are Schiff base forming compounds has been fully considered and deemed persuasive. Therefore, all compounds listed in claim 1 are under examination.

According, claims 1-13 and 24 are currently under examination.

Specification

The drawings are objected to by the Draftsperson under 37 CFR 1.84 or 1.152. Appropriate correction is required (see attached "Notice of Draftsperson's Patent Drawing Review").

The spacing of the lines of the specification is such as to make reading and entry of amendments difficult. New application papers with lines double spaced on good quality paper are required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 10 is drawn to a method of vaccinating a mammal by administering a nucleic acid encoding an antigenic peptide and a Schiff base compound, wherein the Schiff base compound is administered using a gene gun delivery technique. The specification does not teach how to deliver the compound using gene gun. The prior art only teaches delivering nucleic acid to skin by gene gun. The prior art does not teach how to deliver a chemical compound by using gene gun technique. Without the teaching from the art, one skilled in the art would turn to the

specification to look for guidance to use the invention. In the instant case, the specification fails to provide such guidance. Therefore, one skilled in the art would engage in undue experimentation to practice claimed invention.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for deliver the nucleic acid via intramuscular, subcutaneous or intradermal routes by gene gun technique, does not reasonably provide enablement for deliver the nucleic acid via oral, nasal, or pulmonary routes by gene gun technique. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claim 8 is drawn to a method of vaccinating a mammal comprising administering a nucleic acid encoding an antigenic peptide and a Schiff base compound, wherein the nucleic acid is administered via oral, nasal, pulmonary, intramuscular, subcutaneous or intradermal routes using gene gun technique. The specification does not teach how to administer the nucleic acid via oral, nasal and pulmonary route by using gene gun technique. The prior art teaches gene gun delivery of nucleic acid to skin but not other routes. Without the teaching from the art, one skilled in the art would turn to the specification to look for guidance to make/use the invention. In the instant case, the specification fails to provide such guidance. Therefore, one skilled in the art would engage in undue experimentation to practice claimed invention commensurate in scope with these claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "substantially simultaneous" renders the claim indefinite because it is unclear whether administration of the compound and nucleotide is simultaneous or sequential. As such, the metes and bounds of the claim cannot be established.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 7, 8, 9, 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhodes (US 5,508,310) in view of Hermann et al. (US 5,620,896).

The claims are drawn to a method of vaccinating a mammal against a disease state comprising a nucleic acid encoding an antigenic peptide associated with the disease state, and a Schiff base compound, an immuno-potentiating agent, wherein administration of the nucleic acid wherein the administration of nucleotide is achieved by using gene-gun, oral, nasal, pulmonary, intramuscular, subcutaneous, intradermal or topical routes, and the administration of the compound is achieved by oral, nasal, pulmonary, intramuscular, subcutaneous, intradermal or topical routes; and at a dose between 0.1mg and 100mg/per kg per administration.

Rhodes (US 5,508,310) teaches tucaresol (4-(2-formyl-3-hydroxyphenoxymethyl) benzoic acid), a member of Schiff base compound, can be used as vaccine adjuvant, and a vaccine can be prepared by formulating the antigenic component with tucaresol. Rhodes further discloses that the compound can be administered by oral, parenteral and inhalation at a dose range from 0.5 to 50mg/kg per day (see column 9, 7^{th}-9^{th} paragraph). Rhodes further teaches that the mechanism by which Schiff base forming compounds influence immune responses is the same in that compounds react with amino groups on the surface of lymphocytes and antigen presenting cells, therefore providing co-stimulation to T cells, amplifying the co-stimulation provided by physiological Schiff base-formation between ligands on the surface of cells. Rhodes further teaches that low and medium concentration of Schiff base compound will enhance immune responses whereas high concentrations will be inhibitory (see column 16, last paragraph). Rhodes further teaches the dosing of Schiff base compounds used as vaccine adjuvant and routes of administration (see column 9, 8^{th}-10^{th} paragraph). However, Rhodes does not teach the administration of a vector as vaccine via gene-gun, oral, nasal, pulmonary, intramuscular, subcutaneous, intradermal or topical routes.

Herrmann et al. (US 5,620,896) teaches a method of immunizing mammals against rotavirus infections by injecting a vector comprising DNA encoding antigenic peptide to the mammals in the presence of adjuvants (see column (column 7, 2nd–4th paragraph). Hermann et al. further teaches that the vector can be delivered to said mammal via parenteral, intravenous, intraperitoneal, intradermal, subcutaneous, inhalation, or intramuscular routes, or by particle bombardment using a gene gun (see column 7, last paragraph).

Combining the teaching of Rhodes and Herrmann et al., it would have been obvious to one of ordinary skill in the art to practice the method of vaccinating a mammal by administering a nucleotide encoding an antigenic peptide, and augmenting immune response of said vaccine by using Schiff base compound as adjuvant. The ordinary artisan would have been motivated to use Schiff base compound as a vaccine adjuvant because of the teaching of Rhodes, who not only teach those compounds can stimulate immune response but also provides the mechanism of such stimulation. The ordinary artisan would have a reasonable expectation of success because of the teaching of Herrmann et al., who teach a method of vaccinating a mammal by administering a vector comprising DNA encoding an antigenic peptide via parenteral, intravenous, intraperitoneal, intradermal, subcutaneous, inhalation, or intramuscular routes, or by particle bombardment using a gene gun, and the teaching of Rhodes, who teach that Schiff base compound can potentiate immune response. Therefore, the invention is obvious to one of ordinary skill in the art at the time the invention is made.

Claims 2-4, 6 and 24 are objected to because they are dependent on rejected claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J Clark can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.
January 11, 2002

REMY YUCEL, PH.D
PRIMARY EXAMINER